Medical News

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FDA and HCFA Propose Rules for Handling HCV-Infected Blood

The FDA and the Health Care Financing Administration (HCFA) have issued new proposed rules for institutions that handle blood and blood products in an attempt to prevent patients from contracting hepatitis C virus (HCV). Both the FDA's proposed rule and the HCFA's proposed rule appeared in the *Federal Register* on November 16, and both require hospitals and other facilities to develop and adhere to written procedures for appropriate action in handling HCV-infected blood. The rules are intended to create consistent industry standards for potentially infectious blood and blood products. Among the requirements, facilities would establish a "look back," similar to that in effect for HIV, requiring hospitals, when notified by blood banks, to quarantine prior collections from a donor who later tested repeatedly reactive for HCV and to notify transfusion recipients based on further testing of such a donor. HCFA would require the procedures as part of the conditions of participation for Medicare and Medicaid providers.

Comments on the HCFA rule are due January 16, 2001. Send them to HCFA, Department of Health and Human Services, PO Box 8010, Attn: HCFA-3014-P, 7500 Security Blvd, Baltimore, MD 21244-8010.

Both agencies are proposing to extend the record-retention period to 10 years. To read the proposed rules, refer to the November 16 *Federal Register* online, at http://www.access.gpo.gov/su_docs/fedreg/a001116c.html.

JCAHO to Collect Information on Reuse of Single-Use Devices

Beginning in November 2000 and running through approximately March 2001, JCAHO will assist the FDA by distributing educational material regarding the reuse of single-use medical devices to hospitals and by collecting information during on-site surveys about hospital reuse activities.

During the first day of survey, the on-site JCAHO survey team will distribute FDA information regarding the reprocessing of single-use devices and a short questionnaire. Hospital staff will be given the duration of the survey to review the materials, complete the questionnaire, and return it to the survey team. The FDA information and questionnaire also will be sent to hospitals surveyed in September and October 2000. Those organizations will be asked to return the questionnaire directly to JCAHO in a pre-addressed envelope.

JCAHO is acting solely in a role to disseminate and gather information in this project. The results of the questionnaire will not have an impact on an organization's accreditation status. All information gathered will remain anonymous and will be provided to the FDA in aggregate form.

The FDA's main objective in this project is to gather data on the individual devices that fall under the Class III designation, ie, those determined to pose the highest risk.

For questions regarding the Joint Commission's role in this project, contact Kevin Hickey, khickey@jcaho.org or 630-792-5872. More detailed information on device classifications can be accessed on the US Food and Drug Administration Center for Devices and Radiological Health's web site, http://www.fda.gov/cdrh/.

FROM: JCAHO. Inside Perspectives. November 2000. www.jcaho.org.

Alcohol Rubs: CDC's New Hand-Hygiene Guidelines

Waterless alcohol rubs may replace soap and water as the leading recommended tools for hand disinfection in the 2002 Guideline for Hand Hygiene of the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). In November the committee met in Atlanta, Georgia, to review the first draft of the guideline. A second-draft review is tentatively scheduled for May 2001. The shift toward recommending primarily waterless agents stems from the observation that improper handwashing techniques and low compliance with handwashing protocols by healthcare workers (HCWs) make current hand-hygiene recommendations ineffective.

Most handwashing protocols, which call for 30 to 60 seconds of handwashing, bear no resemblance to what actually occurs in healthcare settings. Of 11 studies referenced in the draft that evaluated the average duration of hand washing by HCWs, 8 found averages shorter than 15

seconds, including 6 with averages shorter than 10 seconds. The efficacy of hand washing is based on 30- to 60-second protocols, and there is no evidence evaluating the effectiveness of hand washes that last 7 to 10 seconds. The time demand and inconvenience of repeated hand washing; poor access to handwashing facilities, such as a lack of sinks or sinks that are physically blocked by equipment in patient rooms; and the desire to prevent dermatitis, which can develop after frequent hand washing, contribute to the low compliance with handwashing protocols observed in most healthcare facilities.

Alcohol rubs take less time than washing and effectively reduce microbial loads (although washing is necessary to remove visible soil). Alcohol rubs also provide improved access, as there is no dependence on sinks and plumbing, and improved tolerance, as they can be less irritating to hands than soap and water.

The OSHA Bloodborne Pathogens Standard already requires that HCWs wash hands after removal of gloves and after any potential contact with blood or body fluids, requirements the HICPAC guideline need not reiterate, committee members said.

In related news, HICPAC's *2001 Guideline for Environmental Controls in Healthcare Facilities* is slated for submission to the *Federal Register* by the end of November.

From: Jacobson A. *icanNEWS.* November 7, 2000.

VRE in Children With Bone-Marrow Transplants

The emergence of vancomycin-resistant enterococci (VRE) as nosocomial pathogens is a major problem in the United States; in Europe, VRE nosocomial infections are uncommon and only rarely have been reported in pediatric or neonatal units. Carretto and colleagues from Pavia, Italy, conducted a study to report on the clinical and microbiological features of VRE infections in three children given hematopoietic stem cell transplantation (HSCT). Five episodes of vancomycin-resistant *Enterococcus faecium* (VREF) infection were diagnosed in three children given an allogeneic HSCT. Molecular methods, such as randomly amplified polymorphic DNA (RAPD) fingerprinting and automated ribotyping, were used to define the circulation of strains.

All of the isolates were resistant to all commercially available agents and showed the *van*A genotypic profile. All children were treated successfully with the combination of quinupristin-dalfopristin (QD) plus teicoplanin (TEC), although treatment was not sufficient to eradicate the microorganism promptly from the gastrointestinal tract. All children remain alive. After the first isolation of VRE, a surveillance protocol was started, and they documented that the rate of colonization in children and their mothers was less than 1.5%. The RAPD method demonstrated the possible nosocomial transmission of one strain.

The authors' experience demonstrates that VRE infection is a life-threatening complication in children given HSCT. Prompt diagnosis of this infection and its treatment with the combination of QD and TEC can successfully manage this severe infection in profoundly immunocompromised patients.

FROM: Carretto E, Barbarini D, Locatelli F, Giraldi E, Pellegrini N, Perversi L, et al. Vancomycin-resistant *Enterococcus faecium* infection in three children given allogeneic hematopoietic stem cell transplantation: clinical and microbiologic features. *Haematologica* 2000;85:1158-1164.

Outbreak of *B cereus* Infections in an NICU

In 1998, an outbreak of systemic infections caused by *Bacillus cereus* occurred in the neonatal ICU of the University Hospital Vrije Universiteit, Amsterdam, The Netherlands. Three neonates developed sepsis with positive blood cultures. One neonate died, and the other two neonates recovered. Van Der Zwet and colleagues performed an environmental survey, a prospective surveillance study of neonates, and a case-control study in combination with molecular typing to identify potential sources and transmission routes of infection.

Genotypic fingerprinting by amplified-fragment length polymorphism (AFLP) showed that the three infections were caused by a single clonal type of *B cereus.* The same strain was found in trachea aspirate specimens of 35 other neonates. The case-control study showed mechanical ventilation with a ventilation machine to be a risk factor for colonization or infection (odds ratio, 9.8; 95% confidence interval, 1.1-88.2). Prospective surveillance showed that colonization with *B cereus* occurred exclusively in the respiratory tract of mechanically ventilated neonates. The epidemic strain of *B cereus* was found on the hands of nursing staff and in balloons used for manual ventilation. Sterilization of these balloons ended the outbreak.

The authors concluded that *B cereus* can cause outbreaks of severe opportunistic infection in neonates. Typing by AFLP proved very useful in the identification of the outbreak and in the analysis of strains recovered from the environment to trace the cause of the epidemic.

FROM: Van Der Zwet WC, Parlevliet GA, Savelkoul PH, Stoof J, Kaiser AM, Van Furth AM, et al. Outbreak of *Bacillus cereus* infections in a neonatal intensive care unit traced to balloons used in manual ventilation. *J Clin Microbiol* 2000;38:4131-4136.

Coccidioidomycosis Outbreak: CDC Advisory

A recent outbreak of coccidioidomycosis (CM) among a Pennsylvania church group who did construction work in Mexico indicates a need for healthcare providers to be alert for this disease in returning travelers who have